AN 1668612 PHARMAML
TI Shire's Fosrenol is approvable, says FDA
SO Pharma Marketletter March 10, 2003
DT Newsletter
WC 430
TX . . . HCl] is another treatment option gaining ground) which have been shown to have the potential to cause the bone disease **osteomalacia**. One suggestion is that Shire is being asked to provide more information on the safety of **Fosrenol** with regards to bone, a task which is made the harder because hyperphosphatemia itself is associated with the bone disease renal osteodystrophy. The UK firm has already completed one study supporting the safety of **Fosrenol** on bone (Marketletter June 17, 2002).

Same company as my case's probable assignee

AN 1663684 PHARMAML
TI Shire's Fosrenol clears bone safety hurdle
SO Marketletter June 17, 2002
DT Newsletter
WC 417
TX **Fosrenol** was compared in the study to a reference treatment (calcium carbonate). At baseline, 3% of the **Fosrenol** and calcium carbonate groups exhibited signs of **osteomalacia**, but no evidence of this was found at the end of the study. 15% of **Fosrenol** patients had signs of adynamic bone disease at the outset, compared to 13% of the comparator group. However, while this had disappeared in the **Fosrenol** group by study-end, it was still evident in 10% of the control group.
There was no evidence of low **bone turnover** status in patients treated with **Fosrenol**, although this is encountered in patients receiving standard therapy with calcium carbonate/aluminum hydroxide, said Shire, which also pointed to earlier. . .